MAR 2 - 2005

510(k) Summary of Safety and Effectiveness

K041999

Gyrus PSR System

Submitted by: Gyrus Medical Inc.
6655 Wedgwood Road, Suite 105
Maple Grove, MN 55311-3602

Contact Person: Mark Jensen
Vice President RA/QA

Telephone: 763-416-3005
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Date Summary Prepared: May 5, 2004

Name of the Device:

Proprietary Name: Gyrus Plasma Skin Resurfacing (PSR) System

Common/Usual Name: Electrosurgical Generator and Accessories

Classification Name: Electrosurgical Device (per 21 CFR 878.4400)

Predicate Device: Gyrus Plasma Skin Resurfacing (PSR) System (K023111)

Description: The Gyrus Medical PSR System is intended for treatment of the following dermatological conditions:

- Rhytides of the face
- Superficial skin lesions
- Actinic Keratosis
- Viral papillomata
- Seborrhoeic Keratosis

Accessories included with the generator are a cable assembly/instrument, power cable and a footswitch.

Statement of Intended Use:

The Gyrus PSR System is intended for treatment of dermatological conditions.

This device is intended for use by qualified medical personnel trained in the use of electrosurgery.

Comparison to Predicate Device:

The Gyrus PSR System has been carefully compared to legally marketed devices with respect to intended use and safety and effectiveness. In addition, clinical studies have been done to validate the performance of the device. The clinical data results presented in this 510(k) notification to the FDA show that the device is substantially equivalent to legally marketed devices with respect to intended use and technological characteristics, and is safe and effective in its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 - 2005

Mr. Mark Jensen
Vice President, RA/QA
Gyrus Medical, Inc.
6655 Wedgwood Road, Suite 105
Maple Grove, Minnesota 55311

Re: K041999
Trade/Device Name: Gyrus Plasma Skin Resurfacing (PSR) System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: November 22, 2004
Received: November 23, 2004

Dear Mr. Jensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041999 K041999

Device Name: Gyrus PSR System
ELECTROSURGICAL GENERATOR

Indications For Use:

The Gyrus Medical PSR System is intended for treatment of the following dermatological conditions:

- Rhytides of the face
- Superficial skin lesions
- Actinic Keratosis
- Viral papillomata
- Seborrhoeic Keratosis

The system is intended for use by qualified medical personnel trained in the use of electrosurgical equipment.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041999